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FROM	:	Oleg F. Kaplun, Esq. Fay Kaplun & Marcin, LLP
DATE	:	March 25, 2008
SUBJECT	:	Neurovascular U.S. Patent Appln. Serial No. 10/626,246 for *Embolic Coil* Inventor(s): Elliot Our Ref.: 10123/00601

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MESSAGE:

Please see attached.

Attorney Docket No. 10123/00601 (03-087)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Elliot
Serial No.	:	10/626,246
Filing Date	:	July 24, 2003
For	:	Embolic Coil
Group Art Unit:	:	3731
Confirmation:	:	1009
Examiner	:	Elizabeth Houston

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By: Oleg F. Kaplun, Reg. No. 45,559 Date: March 25, 2008

TRANSMITTAL

Transmitted herewith please find a Reply Brief in response to the Examiner's Answer mailed on January 25, 2008 for filing in the above-identified application. No fees are believed to be required. The Commissioner is hereby authorized to charge any additional required fees to the **Deposit Account of Fay Kaplun & Marcin, LLP No. 50-1492.** A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: March 25, 2008

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PATENT
Attorney Docket No.: 10123 - 00601

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	
Elliot	
Serial No.: 10/626,246	Group Art Unit: 3731
Filed: July 24, 2003	Examiner: Elizabeth Houston
For: EMBOLIC COIL	**Board of Patent Appeals and Interferences**
Confirmation: 1009	

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 C.F.R. § 41.41

In response to the Examiner's Answer mailed on January 25, 2008 to the Appeal Brief filed on October 2, 2007, and pursuant to 37 C.F.R. § 41.41, Appellant presents this reply brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1, 2, 5 - 12, 24 and 26 in the Final Office Action dated April 25, 2007. The appealed claims are set forth in the attached Claims Appendix.

1. Status of the Claims

Claims 1, 2, 5 - 12, 24 and 26 stand rejected in the Final Office Action. Claims 3, 4 and 25 have been canceled. Claims 13 - 23 have been withdrawn. The final rejection of claims 1, 2, 5 - 12, 24 and 26 is being appealed.

2. Grounds of Rejection to be Reviewed on Appeal

I. Whether claims 1, 2, 5 - 11, 24 and 26 are unpatentable under 35 U.S.C. § 103(a) as obvious over Kupiecki (U.S. Patent No. 5,980,514) in view of Villar (U.S. Patent No. 6,287,318

II. Whether claims 5 and 12 are unpatentable under 35 U.S.C. § 103(a) as obvious over Kupiecki in view of Villar and further in view of Ferrera (U.S. Patent No. 6,171,326)

3. Argument

I. The Rejection of Claims 1, 2, 5 - 11, 24 and 26 Under 35 U.S.C. § 103(a) as Obvious Over Kupiecki in View of Villar Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1, 2, 5 - 11, 24 and 26 were rejected under 35 U.S.C. § 103(a) as obvious over Kupiecki in view of Villar. (*See* 4/25/07 Office Action, p. 2). Kupiecki discloses a retaining device comprising a wire 202 wound into a primary helix over an inner core member 204. *Kupiecki*, col. 14, ll. 2 - 7; Fig. 8. The inner core member 204 and primary helix are also wound into a secondary geometry. *Id.* at col. 14, ll. 7 - 9. The inner core member 204 is chosen to provide a desired shape memory and stiffness. *Id.* at col. 14, ll. 33 - 35.

In the Final Office Action the Examiner acknowledges that Kupiecki discloses a coil which does not include any fibers and cites Villar to cure this deficiency. *See* 4/25/07 Office Action, p. 2. Villar discloses a vasso-occlusive device 120 with a helically-wound coil member 122 formed of a biocompatible metallic material. *Villar*, col. 3, ll. 52 - 58; col. 4, ll. 48 - 52; Fig. 2. Coil 122 has a constant diameter but is "somewhat more stretched" so that fibrous elements 126 and 128 are looped through the turns of the coils. *Id.* at col. 4, ll. 49 - 54. Looping filaments 126 and 128 lowers the overall effective diameter of the coil making it easier to deliver through a delivery catheter. *Id.* at col. 4, ll. 54 - 58.

B. The References do not Disclose a Coil with a Plurality of Fibers Gripped Between Adjacent Coils of the Primary Coil as Recited in Claims 1 and 24

Claim 1 recites an embolic coil comprising, "an elongated core element formed of a shape memory material treated to define a memorized secondary coil shape" and "an elongated outer

element wound around the elongated core element to define a primary coil shape of the embolic coil" in combination with "a plurality of fibers *gripped between* adjacent coils of the primary coil."

In the final rejection, the Examiner acknowledges that Kupiecki does not disclose a coil having fibers as recited in claim 1 and cites Villar to cure this deficiency. However, it is respectfully submitted that Villar does not cure this deficiency because it does not teach or suggest "a plurality of fibers *gripped between* adjacent coils of the primary coil," as recited in claim 1.

In fact, Villar specifically teaches away from fibers gripped between adjacent coils. The embodiment including the fibers is described as having coils that are "more stretched." *Id.* at col. 4, ll. 49 - 54. "Stretched" coils are spread away from one another and are incapable of gripping fibers between them -- i.e., these stretched coils provide no pressure on any fibers received therebetween. The term "gripped" is defined as "to secure and maintain a tight hold on; seize firmly" according to the *American Heritage Dictionary of the English Language, Fourth Edition.* The primary coil will be unable to "secure and maintain a tight hold" on the fibers between its adjacent coils if the coils are not tightly wound together. In this embodiment, Villar has made clear that the coils are stretched, not tightly wound, and that the fibers are only loosely looped through the coils.

In addition, Villar specifically describes attaching the fibers to the core member by glues or by heating the polymers to maintain contact with the core member 122. *Villar* at col. 5, ll. 21 - 26. Any attachment would thus exist only at the point at which the fiber touches the core member 122. As can be seen in Fig. 2, such contact exists on the inner curve of the looped coil, and not *between* the adjacent coils.

The Examiner contends that there is no clear definition for "gripped" given in the specification and thus the words of the claim must be given their plain meaning. *See* 1/25/08 Examiner's Answer, p. 8. The Examiner defines "grip" as "a manner of grasping and holding" and states that this is the broadest reasonable definition. *Id.* Applicant respectfully submits that this definition is consistent with the definition provided by Applicant. It is respectfully submitted that "grasping and holding" has a meaning in standard English and as would be understood by those skilled in the art substantially the same as "securing and maintaining a tight hold." Specifically, grasp is defined as "to clutch at, to seize and hold by clasping or embracing with or as if with the fingers or arms." Webster's Third International Dictionary - Unabridged, 1986. It is respectfully submitted that the coils of Villar do not "grasp and hold" the fibers, but merely contact the fibers as they are either looped through the coils or attached via heat and/or glue. The Examiner's interpretation of the term gripped would suggest that any attachment of the fibers to the coils (e.g., gluing, or welding) constitutes a *gripping*. It is respectfully submitted that this interpretation is in no way supported by the meaning of the very words the Examiner cites to support it and that, to be gripped between adjacent coils, the fibers must be squeezed therebetween.

Thus, when read as a whole, the limitation of "gripped between adjacent coils," as recited in claim 1, is quite clear and requires fibers held securely *between* coils that are next to one another.

Therefore, it is respectfully submitted that neither of the cited references either shows or suggests such gripped fibers and not only do these references provide no motivation for the modification suggested by the Examiner, they actually teach away from it. It is therefore respectfully submitted that claim 1 is not rendered obvious by Kupiecki and Villar taken either alone or in combination and withdrawal of this rejection is requested. Because claims 2 and 5 -

11 depend from, and therefore include, all of the limitations of claim 1, it is respectfully submitted that the rejection of these claims should also be reversed.

Claim 24 recites a coiled medical device for implantation in a patient comprising, "a primary coil having a primary coil shape, the primary coil defining a lumen extending therethrough" and "a secondary coil formed of a shape memory material and disposed in the lumen , the secondary coil having a secondary coil memorized shape, wherein, when heated to a temperature above a critical temperature of the shape memory material, the secondary coil causes the primary coil to follow the secondary coil shape" in combination with "a plurality of fibers *gripped between* adjacent coils of the primary coil."

For at least the same reasons as stated above in regard to the § 103(a) rejection of claim 1, it is respectfully submitted that claim 24 is also not rendered obvious by Kupiecki and Villar taken either alone or in combination and that this rejection should also be reversed. Because claim 26 depends from, and therefore includes, all of the limitations of claim 24, it is respectfully submitted that this claim is also allowable and the rejection of this claim should be reversed.

II. The Rejection of Claims 5 and 12 Under § 103(a) as Obvious over Kupiecki and Villar in Further View of Ferrera Should be Reversed

A. The Examiner's Rejection

In the Examiner's Answer, claims 5 and 12 were rejected under 35 U.S.C. 103(a) as obvious over Kupiecki in view of Villar and in further view of Ferrera (See 1/25/08 Examiner's Answer, p. 5). The Examiner states that Kupiecki in view of Villar discloses all of the limitations of the instant invention substantially as claimed except for applying cold work to the outer element and the outer element comprising a platinum wire co-wound with a shape memory material. *Id.* The Examiner cites Ferrera to cure these deficiencies. Ferrera discloses a helically wound vasoocclusive coil 1 comprising a distal portion 8 having a second operable, three

dimensional shape for filling the anatomical cavity at the site in the vasculature to be treated, and a proximal portion having a second operable, substantially linear shape for filling and reinforcing the distal, three dimensional shaped portion when the vasso-occlusive is implanted at the site in the vasculature to be treated. *Ferrera*, col. 6, ll. 33 - 40. The vasso-occlusive coils may be formed from a multi-stranded microcable in order to prevent kinks and breakage. *Id.* at col. 6, ll. 47 - 49 and col. 7, ll. 5 - 10.

B. The References do not Disclose an Embolic Coil Comprising a Plurality of Fibers Gripped Between Adjacent Coils Recited in Independent Claim 1

Claim 1 has been recited above and discussed with reference to Kupiecki in view of Villar. It is respectfully submitted that Ferrera does not cure the deficiencies of Kupiecki in view of Villar described above in regard to independent claim 1. Specifically, Ferrera does not show or suggest "a plurality of fibers *gripped between* adjacent coils of the primary coil," as recited in claim 1. Because claims 5 and 12 depend from, and therefore include, all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable and the rejection of these claims should be reversed.

4. Conclusion

For the reasons set forth above, Appellant respectfully requests that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) and indicate that claims 1, 2, 5 - 12, 24 and 26 are allowable.

Respectfully submitted,

Date: March 25, 2008

By: _____
Oleg F. Kaplun (Reg. No. 45,559)

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CLAIMS APPENDIX

1. (Previously Presented) An embolic coil comprising:

an elongated core element formed of a shape memory material treated to define a memorized secondary coil shape;

an elongated outer element wound around the elongated core element to define a primary coil shape of the embolic coil; and

a plurality of fibers gripped between adjacent coils of the primary coil.

2. (Original) The embolic coil according to claim 1, wherein the shape memory material of which the elongated core element is formed is, at an operational temperature of the embolic coil, in an austenitic phase.

3. (Canceled)

4. (Canceled)

5. (Original) The embolic coil according to claim 1, wherein a shape of the primary coil is defined by applying cold work to the elongated outer element.

6. (Original) The embolic coil according to claim 1, wherein the memorized shape of the elongated core element is substantially a coil.

7. (Original) The embolic coil according to claim 1, wherein the memorized shape of the elongated core element is substantially a three dimensional spiral.

8. (Original) The embolic coil according to claim 1, wherein the shape memory material of which the elongated core element is formed includes Nitinol.

9. (Original) The embolic coil according to claim 1, wherein the elongated outer element is formed of platinum.

10. (Original) The embolic coil according to claim 1, wherein the primary coil shape is a substantially cylindrical coil.

11. (Original) The embolic coil according to claim 1, further comprising a plurality of fiber retention grooves formed of the elongated core element.

12. (Original) The embolic coil according to claim 1, wherein the elongated outer element comprises a platinum wire co-wound with a wire formed of a shape memory material.

13. (Withdrawn) A method of forming an embolic coil, comprising the steps of:

imparting a memorized shape to a core element formed of a shape memory material, wherein the memorized shape defines a secondary coil of the embolic coil;

straightening the core element;

winding an elongated outer element around the straightened core element to form a primary coil of the embolic coil; and

releasing the straightened core element when the device has been positioned at a deployment location to form the secondary coil of the embolic coil.

14. (Withdrawn) The method according to claim 13, further comprising the step of attaching fibers to the embolic coil.

15. (Withdrawn) The method according to claim 14, wherein the fibers are attached to the primary coil.

16. (Withdrawn) The method according to claim 14, wherein the fibers are attached to

grooves formed in the core element.

17. (Withdrawn) The method according to claim 13, further comprising the step of cooling the shape memory core element below a critical temperature before straightening the core element.

18. (Withdrawn) The method according to claim 13, wherein the core element is released in an environment having a temperature above a critical temperature of the shape memory material.

19. (Withdrawn) The method according to claim 13, wherein the secondary coil shape is one of a spiral, helix, vortex, and three-dimensional spriral.

20. (Withdrawn) The method according to claim 13, wherein the elongated outer element is formed of a platinum wire.

21. (Withdrawn) The method according to claim 20, further comprising the step of co-winding the platinum wire with wire formed of a shape memory material.

22. (Withdrawn) The method according to claim 13, wherein the core element is formed of a Nitinol wire.

23. (Withdrawn) The method according to claim 13, further comprising the step of forming fiber retention grooves in the core element.

24. (Previously Presented) A coiled medical device for implantation in a patient comprising:

a primary coil having a primary coil shape, the primary coil defining a lumen extending therethrough;

a secondary coil formed of a shape memory material and disposed in the lumen, the secondary coil having a secondary coil memorized shape, wherein, when heated to a

temperature above a critical temperature of the shape memory material, the secondary coil causes the primary coil to follow the secondary coil shape; and

a plurality of fibers gripped between adjacent coils of the primary coil.

25. (Canceled)

26. (Original) The medical device according to claim 24, wherein the shape memory material includes Nitinol.